REMARKS

Applicants' appreciate the courtesy of the examiner during the interview of June 2, 2009. The references of record were discussed and distinguished with respect to claim 1. Further, all the claims were discussed in light of the secondary considerations recited in the present amendment. No agreement was reached with respect to the allowance of any claim, however, specific claims terms were discussed in an effort to bring the claims in condition fro allowance.

This paper is intended as a full and complete reply to the Office Action dated March 3, 2009, having a shortened statutory period set to expire on June 3, 2009.

Claims 1-4, 6-10, and 22-24 are pending in the application.

Claims 1, 2, and 22-24 are currently amended in this response.

Claims 5 and 11-21 have been cancelled.

Specification Objections

The Office Action objected to the amendment filed 11/17/08 under 35 USC 132(a), as new matter, due added recitations "general purpose computer" and "electronic" patterns within Claims 1 and 22-24.

Applicant has amended the above-referenced claims to remove these recitations and believes the objections are thereby overcome.

Claim Rejections 35 USC §112

Claims 1 and 22-24 stand rejected under 35 USC §112, first paragraph, as failing to comply with the written description requirement.

Applicant has amended the above-referenced claims to remove the recitations "general purpose computer" and "electronic" patterns and believes these amendments overcome the stated rejections.

Claim Rejections 35 USC §103

Claims 1-4 and 6 stand rejected under 35 USC §103(a) as being unpatentable over Cunningham (6,859,780) in view of Borsand et al. (2003/0074225). Applicant respectfully traverses this rejection.

The analysis to determine whether the claimed invention meets the statutory conditions for patentability under 35 U.S.C. §103 requires that "obviousness," which is a legal term of art, be evaluated in each individual situation. More specifically, under *Graham v. John Deere Co.*, 383 U.S. 1, 148 U.S.P.Q. 459 (1966), obviousness must be determined based upon the following considerations:

1. The scope and content of the prior art;
2. The differences between the subject matter sought to be patented and the prior art;
3. The time at which the invention was made;
4. The level of skill of a person having ordinary skill in the art to which the invention pertains; and
5. Objective evidence indicating obviousness or nonobviousness, i.e. evaluating whether the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art.

Claim 1 recites a method usable to track prescription medication and control drug abuse that includes providing computer connections to both affiliated and unaffiliated pharmacies, obtaining and storing pharmaceutical data related to prescriptive medication purchases by a plurality of purchasers from both the affiliated and unaffiliated pharmacies, and selectively transferring the data to at least one of the entities to obtain to obtain a complete prescriptive history for a selected purchaser. Claim 1 combines and utilizes data from pharmacies that are affiliated with one another (i.e., two locations within a pharmacy chain that maintain a common database of information), as well as pharmacies that are unaffiliated with one another (that do not maintain a common database of information). (Applicant's Specification, Paragraph [0061]). The prescriptive history is based on all medications purchased in the aggregate, by a selected purchaser, from all of the affiliated and unaffiliated pharmacies. The complete prescriptive history is then used to generate patterns that flag prescriptive drug abuse, such as prescription duplication, multi-source prescription abuse, and similar patterns. (Applicant's Specification, Paragraph [0070])

Applicant's method is specifically adapted for tracking controlled substances, preventing abuse, and managing prescription information in the aggregate, through use of an independent "clearinghouse" of prescriptive information. Continuously updatable information from both affiliated and non-affiliated parties is thereby accessible, in real time, and in context. An unbiased method is thereby provided which prevents prescriptive drug abuse, medical complications and death, and saves billions of dollars in healthcare costs and related costs to third party providers, insurers, and governmental programs.

The cited references, Cunningham in view of Borsand, neither alone, nor in combination, teach each element of the claimed invention.

Cunningham does not teach a system adapted for preventing prescriptive drug abuse and instead describes a system used to track product media, i.e. tracking a clinical trial and/or sample pharmaceutical products. Cunningham describes that prescribers are given encoded media, such as a magnetic card, which are activated by the prescriber

through connection to a central computing station before distribution to a patient, who then exchanges the activated media at a pharmacy for corresponding products. (Cunningham, Column 2, Line 64 – Column 3, Line 34). After activation of the media, and after validation of the media and dispensation of product, a database records the transactions, enabling audit and accounting procedures, which facilitates replenishment of dispensed products and payment of fees. (Cunningham, Column 3, Lines 40-53).

Cunningham fails to teach using pharmaceutical data acquired through computer connections to various entities to obtain a complete prescription history for a purchaser. Cunningham describes only discrete tracking of individual transactions, such as activation, validation, and dispensation, to facilitate performance of specific and discrete responses to these individual transactions, such as replenishment of product and payment of reimbursement. Cunningham does not disclose or suggest obtaining a complete prescriptive history.

Cunningham further fails to teach or suggest generating patterns that flag rescriptive drug abuse. Cunningham instead describes use of an activated product medium as a prescription form indicating a product and quantity/dose, which is validated upon dispensation. The system described by Cunningham does not track or generate patterns of any kind, related or unrelated to drug abuse, and instead simply records individual pharmaceutical transactions.

Cunningham defines the level of skill of a person having ordinary skill in the art to which the claimed invention pertains, and clearly teaches away from the claimed invention. Cunningham is silent concerning the primary function of the claimed invention, namely, Cunningham does not provide a prescription history for preventing prescription drug abuse. Cunningham further teaches away from the claimed invention by specifically being adapted to be applicable to only a small, selected number of prescription drug users, namely, those involved in product or clinical trials for testing a drug's efficacy. (See, e.g., Cunningham, Figures 1-4 and 6). The claimed invention, conversely, provides a complete prescriptive history for preventing prescription drug abuse.

Borsand describes a system for tracking prescription information and communicating this information between payors, pharmacy benefit managers, pharmacies, and providers using a centralized location ("Pharmacy Benefit Manager") for storing the information. (Borsand, Paragraphs [0010] and [0011]). The system can be consulted prior to issuing a prescription, filling a prescription, or refilling a prescription. (Borsand, Paragraph [0011]).

Borsand fails to teach the elements of Claim 1 not taught by Cunningham. Specifically, Borsand does not teach using pharmaceutical data acquired through computer connections to various entities to obtain a complete prescriptive history for a purchaser. Similar to Cunningham, Borsand describes only discrete tracking of individual transactions to enable providers to pre-certify prescriptions prior to issuance, enable consultation with protocols and guidelines by a pharmacy prior to filling the prescription, and to enable refill activites of a patient to be monitored. (Borsand, Paragraph [0011]). Borsand fails to teach or suggest a complete prescriptive history of a selected prescriptive medication purchaser for all prescriptive medications purchased in the aggregate by the purchaser from all affiliated and unaffiliated pharmacies.

Additionally, Borsand does not teach or suggest generating patterns that flag or identify prescription drug abuse. Borsand describes that prescriptions can be cancelled or refills declined on an individual basis, such as when a patient's course of treatment is changed, but Borsand does not disclose using a purchaser's complete prescription history to generate patterns that flag prescription drug abuse.

Borsand teaches away from the claimed invention. Borsand describes tracking payments using a "Pharmacy Benefit Manager," focused on the monetary aspect of the prescriptive medication business. Borsand is silent concerning the primary function of the claimed invention, namely, to provide a prescription history for preventing prescription drug abuse.

Numerous secondary considerations further illustrate the uniqueness and nonobviousness of the claimed invention.

A long felt need exists for a method for tracking prescriptive medication, to address and control prescription drug abuse and other related errors. This need has not been met by existing systems that simply track individual instances of prescription issuance or dispensing of a product. The number of deaths related to prescription medication errors in the United States exceeded 8000 in 1993. Adverse events related to prescription drugs are responsible for an estimated 75 billion dollars in costs, per year, as of 2005. Both Cunningham and Borsand provide methods that teach away from providing a prescription history for preventing prescription drug abuse, and illustrate the long felt need for the claimed invention.

Applicant's claimed method has experienced great commercial success, decreasing adverse events related to prescriptive medication by as much as 84% in some locations. A reduction in prescriptive medication abuse and related errors by as little as 15% can save 15 billion dollars annually.

The differences between the prior art and the claimed invention provide an additional secondary consideration indicating the nonobviousness of the claimed invention. Cunningham tracks the efficacy of a product or clinical trial using media, and Borsand tracks payment for prescription drugs. Were the claimed invention to be practiced using the methodology defined by Cunningham or Borsand, the claimed invention would be inoperable for its intended purpose to prevent prescription drug abuse.

A further secondary consideration that weighs in favor of nonobviousness of the claimed invention is the available of art utilized to those skilled in the art without such individuals recognizing the significance of the claimed invention. For example, the use of tracking clinical trials and tracking payment for prescription drugs is known, but use of a prescription history for preventing prescription drug abuse is unique and nonobvious in light of these teachings.

Additionally, the failure of established competitors in a highly competitive market to create the present invention, despite the incentive to do so, further indicates the nonobviousness of the claimed invention. The claimed invention is a significant

advancement in the art that enhances the determination of a problem that may exist intentionally or unintentionally. This effective determination is critical, the claimed invention solving a problem that a competitive market has previously failed to solve.

Further, the claimed invention provides benefits not realized previously by known methodologies by quickly defining a prescription history and speeding the awareness of and prevention of prescription drug abuse.

The results obtained by the claimed invention are new and unexpected, and are suggested nowhere in the prior art. The cited references are silent concerning creation of a complete prescruiptive history and using this history to prevent prescription drug abuse.

Finally, the evaluation of the claimed invention as a whole, considering the claimed structure and/or metholodgy, as well as its properties and the problem solved, reveals a unique, nonobvious method. The prior art teaches away from the claimed invention, failing to describe obtaining a complete prescriptive history for preventing prescription drug abuse.

As such, Applicant believes that the combination of Cunningham and Borsand fails to teach each element of Claim 1, and that for the reasons described above, numerous secondary considerations weigh in favor of the nonobviousness of the claimed invention.

Claims 2-4 and 6 depend from Claim 1 and contain all limitations thereof. Because Applicant believes Claim 1 is patentable over Cunningham in view of Borsand, Applicant believes that Claims 2-4 and 6 are also patentable over the art of record.

Claims 7-10 stand rejected under 35 USC §103(a) as being unpatentable over Cunningham (6,859,780) in view of Borsand et al. (2003/0074225), and further in view of Munoz et al (2002/0052760). Applicant respectfully traverses this rejection.

Munoz describes an automated prescription administration system accessable via telephone using DTMF tones interconnected with databases. (Munoz, Paragraph [0001]).

A prescription request is used to create a database entry, the pharmacist identifying a product to be dispensed using a NCD number and commercial name of the product, which is coupled with patient information and a unique tracking number to prevent accidental improper dispensing of a product. (Munoz, Paragraphs [0016] – [0018]).

Munoz fails to teach the elements of Claim 1 not taught by Cunningham or Borsand. Specifically, Munoz does not teach or suggest a method for tracking prescriptive medication, to address and control prescription drug abuse, that includes obtaining a complete prescriptive history and generating from this complete prescriptive history patters which flag prescriptive drug abuse.

Claims 7 – 10 depend from Claim 1 and contain all limitations thereof. Because Applicant believes Claim 1 is patentable over Cunningham in view of Borsand, further in view of Munoz, Applicant believes that Claims 7-10 are also patentable over the art of record.

Claim 22 stands rejected under 35 USC §103(a) as being unpatentable over Cunningham (6.859.780) in view of Rice et al (2002/0042723). Applicant respectfully traverses this rejection.

Claim 22 recites a method for tracking prescriptive medications to address and control prescriptive drug use, in which computer connections are to multiple entities, including hospitals, doctors, and/or one or more government agencies. Pharmaceutical computer data relating to prescriptive medication purchases by a plurality of purchasers is obtained from a plurality of pharmacies and stored. This pharmaceutical computer data is then selectively transferred to at least one entity to obtain a complete prescriptive history for a selected purchaser, the complete history including all prescriptive medications purchased in the aggregate by the selected prescriptive medication purchaser from all of the plurality of pharmacies. The complete prescriptive history is then used to generate patterns that flag prescriptive drug abuse.

As described above, Cunningham fails to teach using pharmaceutical data acquired through computer connections to various entities to obtain a complete

prescriptive history for a purchaser, or use of the complete prescriptive history to generate patterns that flag prescriptive drug abuse.

Rice describes a healthcare network usable to provide FDA alerts and other types of alerts, such as changes in a patient's status, to various consumers, including doctors, patients, nurses, home health care agencies, and/or hospitals. (Rice, Abstract and Paragraph [0005]). In operation, networked computers are used to review patent information and evaluate alert information generated by a healthcare agency. (Rice, Paragraphs [0008] and [0009]).

Rice fails to teach the element of Claim 22 not taught by Cunningham. Rice does not teach or suggest a method for tracking prescriptive medications and control prescription drug abuse and instead relates to the transmission of alerts and changes in patient information to various healthcare providers.

Specifically, Rice fails to teach use of pharmaceutical computer data to obtain a complete prescriptive history of a purchaser, and further fails to teach use of the complete prescriptive history to generate patterns which flag prescriptive drug abuse.

As such, Applicant believes that Claim 22 is patentable over Cunningham in view of Rice.

Claim 23 stands rejected under 35 USC §103(a) as being unpatentable over Cunningham (6,859,780) in view of Rice et al (2002/0042723), and further in view of Edelson et al. (5,737,539). Applicant respectfully traverses this rejection.

Edelson describes an electronic prescription creation system, which accesses remote databases to obtain formulary and patient history information. (Edelson, Abstract) A patient condition or problem is associated with each drug prescribed to memorialize a physician's intent and treatment objectives. (Edelson, Column 4, Lines 43-45).

Edelson fails to teach the elements of Claim 22 not taught by Cunningham and Rice. Specifically, Edelson fails to teach use of pharmaceutical computer data to obtain a complete prescriptive history of a purchaser, and further fails to teach use of the complete prescriptive history to generate patterns, which flag prescriptive drug abuse. Edelson instead describes obtaining discrete, individual items of information for the purpose of making decisions regarding which drugs to prescribe, and does not teach or suggest obtaining a complete prescriptive history of a purchaser for purposes of flagging and preventing prescriptive drug abuse.

Claim 23 depends from Claim 22 and contains all limitations thereof. Because Applicant believes Claim 22 is patentable over Cunningham in view of Rice, further in view of Edelson, Applicant believes that Claim 23 is also patentable over the art of record.

Claim 24 stands rejected under 35 USC §103(a) as being unpatentable over Cunningham (6,859,780) in view of Borsand et al. (2003/0074225)), and further in view of Edelson et al. (5,737,539). Applicant respectfully traverses this rejection.

As described previously, neither Cunningham, Borsand, nor Edelson teach each element of Claim 22. Specifically, the art of record fails to teach or suggest use of pharmaceutical computer data to obtain a complete prescriptive history of a purchaser, and further fails to teach use of the complete prescriptive history to generate patterns which flag prescriptive drug abuse.

Claim 24 depends from Claim 22 and contains all limitations thereof. Because Applicant believes Claim 22 is patentable over Cunningham in view of Borsand, further in view of Edelson, Applicant believes that Claim 24 is also patentable over the art of record.

Conclusion

In light of the above discussion, Applicant respectfully submits that the application now stands in prima facie condition for allowance and courteously requests that this application be advanced to issue. The Applicant is of the opinion that no fees are required. However, if fees are required, the Commissioner is hereby respectfully authorized to deduct such fees from Deposit Account Number 13-2166.

The Examiner is respectfully invited to call the Applicant's representative at 713-355-4200, to discuss any matters that may arise, where such discussion may resolve such matters and place this application in condition for allowance.

Respectfully Submitted,

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